510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k061137

B. Purpose for Submission:
New device

C. Measurand:
Controls for complexed PSA (cPSA)

D. Type of Test:
Assayed Quality Control material

E. Applicant:
Bayer Diagnostics

F. Proprietary and Established Names:
Bayer ADVIA® IMS cPSA Controls

G. Regulatory Information:

1. Regulation section:
   21 CFR §862.1660, Quality Control Material (assayed and unassayed)
2. Classification:
   Class I, reserved
3. Product code:
   JJY, Multi-analyte controls, all kinds (assayed and unassayed)
4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   For in vitro diagnostic use to monitor the precision and the accuracy of the assayed, quantitative complexed PSA assays on the ADVIA® IMS and Bayer Immuno1® systems.
2. Indication(s) for use:
   For in vitro diagnostic use to monitor the precision and the accuracy of the assayed, quantitative complexed PSA assays on the ADVIA® IMS and Bayer Immuno1® systems.
3. Special conditions for use statement(s):
   For prescription use only.
4. Special instrument requirements:
   ADVIA® IMS system and Bayer Immuno1® system

I. Device Description:

The Bayer ADVIA® IMS cPSA Controls are bovine serum based with non-serum constituents added. The analyte in the control material is cPSA. The cPSA control kit consists of three different levels of control materials. Level 1 control is manufactured to a clinically significant decision point, between normal and patient groups. Level 3 control is manufactured to the upper analytical range of the assay. Level 2 control is manufactured to a level in between Level 1 and Level 3 controls.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bayer Special Chemistry Controls

2. Predicate 510(k) number(s):
   k033379
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Bayer ADVIA® IMS cPSA Controls are intended for in vitro diagnostic use to monitor the precision and the accuracy of the assayed, quantitative complexed PSA method on immunoassay systems including the ADVIA® IMS and Bayer Immuno1® systems	Bayer special chemistry controls are intended for in vitro diagnostic use in the control of ADVIA chemistry system for certain chemistry methods

Differences		
Item	Device	Predicate
Constituent analytes	cPSA	Acid phosphatase Lactate Lipase Pancreatic Amylase Cholinesterase Total iron binding capacity
Format	Bovine serum based with human constituents Liquid form and ready to use.	Human serum based with human and bovine constituents Lyophilized
Levels	Three levels	Two levels
Stability	Stable until the expiration date on the label when unopened and stored at <= -10ºC. Stable for 35 days when opened and stored at 2-8ºC.	Stable at 2-8ºC until the expiration date printed on the label. Stable 7 days when reconstituted and stored at 2-8ºC.

K. Standard/Guidance Document Referenced (if applicable):

Guidance for Industry "Points to consider guidance document on assayed and unassayed quality control material".

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      Not applicable.
   b. *Linearity/assay reportable range:*
      Not applicable.
   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
      The ADVIA IMS cPSA controls are traceable to Stanford University PSA reference material. This standard consists of 90% purified PSA-α_1-antichymotrypsin (ACT) and 10% free PSA (90:10) mixture on a molar basis. Value assignment of production lots is done by a nested study that uses a Master Lot of product traceable to the Stanford PSA standard.

      Unopened controls are stable when stored at <= -10ºC in a non frost-free freezer, until the expiration date on the label. Opened controls are stable for 35 days, when stored at 2-8ºC.
   d. *Detection limit:*
      Not applicable
   e. *Analytical specificity:*
      Not applicable.
   f. *Assay cut-off:*
      Not applicable.
2. Comparison studies:
   a. *Method comparison with predicate device:*
      Not applicable.
   b. *Matrix comparison:*
      Not applicable.
3. Clinical studies:
   a. *Clinical Sensitivity:*
      Not applicable.
   b. *Clinical specificity:*
      Not applicable.
   c. *Other clinical supportive data (when a. and b. are not applicable)*:
      Not applicable
4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.